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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/805,652	03/13/2001	D. Laksen Sirimanne	412692000401	4202

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MORRISON & FOERSTER LLP
755 PAGE MILL RD
PALO ALTO, CA 94304-1018

EXAMINER	
JUNG, WILLIAM C	
ART UNIT	PAPER NUMBER
3737	

DATE MAILED: 01/14/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/805,652	SIRIMANNE ET AL.	
	Examiner	Art Unit	
	William Jung	3737	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *07 June 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-43* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-43* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *24082003*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Response to Arguments

1. Applicant's arguments with respect to claims 1-3, 7-10, 14, 15, 21-24, 26, and 31 have been considered but are moot in view of the new ground(s) of rejection.

Double Patenting

2. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington,* 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

3. Claim 1 is provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 1 of copending Application No. 10/114,712 in view of ***Stinson et al*** (US 6,340,367).

Although the conflicting claims are not identical, they are not patentably distinct from each other because both claim a filler body comprising a resilient bioabsorbable material, and at least one marker. The instant application is narrower than the '712 application with regards of having the marker affixed to the filler body to mark a particular section of the filler body. However, it is obvious to one of ordinary skill in the art of medical device location that a marker would locate at least a particular part of the body. In addition, the limitation of removing foreign materials or excess tissue is taught by Stinson et al's device. Therefore, it would have been

obvious to one of ordinary skill in the art to utilize Stinson et al's device to remove materials in the body to achieve the same limitation added by the amendment.

This is a provisional obviousness-type double patenting rejection.

Claim Rejections - 35 USC § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

5. Claims 1-15 and 19-43 are rejected under 35 U.S.C. 103(a) as being unpatentable over ***Stinson et al*** (US 6,340,367).

Stinson teaches a filler radiopaque marker (column 15, lines 8-28) implanted into a filler body, in the form of the stent, which fills a atherosclerotic blood vessel, at a particular section of the stent, (Figure 12, item 24) as in claims 1, 2, 7, 29, and 31,comprising the following structures:

-Marker comprising a non-bioabsorbable material, such a gold, as in claim 3 (column 13, lines 50-60).

-Radiopaque body, as in claim 8 (column 1, lines 43-52)

-Echogenic marker and body, as in claims 9 and 10 (column 2, lines 35-48).

-Marker within and about the filler body, as in claims 14 and 15 (Figure 12).

-Marker in form of a band, suture, or wire, weaved in to the filler body, which would leave a distinguishing mark, as in claims 21-24 and 26 (Figure 12).

-Wherein the stent is of a irregular shape (Figure 12).

Although Stinson et al do not specifically disclose a removal of the tissue subcutaneously to create cavity, Stinson et al's device is substantially the same as in removing foreign material such as radiopaque markers within the tissue invasively. Thus, Stinson et al's device can serve as removing any materials in the body. Therefore, it would have been obvious to one having an ordinary skill in the art at the time the invention was made to adapt Stinson et al's device to creative tissue cavity.

Claim 3: Stinson et al disclose a marker comprising a material selected from a group consisting of platinum, iridium, nickel, tungsten, tanalum, gold, silver, rhodium, titanium, alloys, and stainless steel (col. 4, lines 45-48).

Claims 4-6, 11-13, 27, 28, 32, and 39-43 : Stinson et al also disclose a use of at least one marker comprises a bioabsorbable material placed within a body as a radiopaque marker. Furthermore, the radiopaque marker may be a polymer. Moreover, the composition of the polymer marker may include a group consisting of barium, bismuth, tantalum, tungsten, barium carbonate, bismuth oxide, and barium sulfate. These markers have specific radiopaque characteristics (x-ray) of that is palpable within the tissue, especially in soft tissue such as breast. Therefore, the combination of materials for x-ray radiopaque marker used in soft tissue renders obviousness to mammographic imaging (col. 3, line 60 – col. 5, line 6).

Claims 19, 20, 25, 30, and 33-35: The shape and structure of the markers are disclosed by Stinson et al to be elongated or spherical. Thus, Stinson et al demonstrates that the shape of the markers is flexible to any configuration to apply within the body (col. 5, lines 49-62). Therefore, the mark structural features as claimed in claims 19, 20, 25, 30, and 33-35 are obvious under Stinson et al's teaching.

6. Claims 16 and 17 are rejected under 35 U.S.C. 103(a) as being unpatentable over ***Stinson et al*** as applied to claim 1 above, and further in view of ***Roth et al*** (US 5,665,063).

Stinson et al substantially disclosed all claimed features in claims 16 and 17. However, Stinson et al do not disclose that the radiopaque material have therapeutic or hemostatic function. Roth et al disclose that radiopaque marker is used where the structure containing the marker acts a hemostatic valve and the markers may contain drugs having therapeutic effect (col. 3, line 66 – col. 4, line 14; col. 8, line 49 – col. 9, line 14). Therefore, it would have been obvious to one having an ordinary skill in the art at the time the invention was made to apply Roth et al's therapeutic and hemostatic markers to improve Stinson et al's device.

7. Claim 18 is rejected under 35 U.S.C. 103(a) as being unpatentable over ***Stinson et al*** as applied to claim1 above, and further in view of ***Wolff et al*** (US 5,997,468).

Stinson meets all the claims except that it fails to teach a particular bioabsorbable filler body material. Wolff teaches a bioabsorbable stent that could be made from synthetic polymers such as polyphosphate esters (column 8, lines 13-67 and column 9, lines 1-20). It would have been obvious to one having ordinary skill in the art at the time the invention was made to adapt Wolff et al teaching to Stinson's device such that there would be less potential for tissue inflammation.

Conclusion

8. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to William Jung, Ph.D. whose telephone number is 571-272-4739. The examiner can normally be reached on Mon-Fri 8:30 AM to 5 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brian Casler can be reached on 571-272-4956. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

WJ

January 8, 2005

ELENI MANTIS-MERCADER
PRIMARY EXAMINER

ELENI MANTIS-MERCADER
PRIMARY EXAMINER